PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
GRID 101		
International application No.	International filing date (*day/month/year*)	Priority Date (*day/month/year*)
PCT/IN 2005/000091	24 March 2005 (24.03.2005)	25 March 2004 (25.03.2004)

International Patent Classification (IPC) or national classification and IPC

IPC[8]: ***A61K 9/30*** (2006.01); ***A61K 9/56*** (2006.01)

Applicant

SUN PHARMACEUTICAL INDUSTRIES LIMITED ET AL

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I. ☒ Basis of the opinion
   - II. ☐ Priority
   - III. ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV. ☐ Lack of unity of invention
   - V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI. ☐ Certain documents cited
   - VII. ☒ Certain defects in the international application
   - VIII. ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11 October 2005 (11.10.2005)	11 August 2006 (11.08.2006)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer KRENN M. Telephone No. 1/53424/435

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1-38, 41(abstract) , as originally filed
pages _____ , filed with the demand
pages _____, filed with the letter of _____.

☒ the claims:
pages _____ , as originally filed
pages _____ , as amended (together with any statement) under Article 19
pages _____ , filed with the demand
pages 39-40 , filed with the letter of 8 March 2006 (08.03.2006).

☐ the drawings:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/ or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 4, 5, 11, 12.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 4, 5, 11, 12 are so unclear that no meaningful opinion could be formed *(specify)*:

Claims 4 and 11 are functional claims, because they do not disclose how an immediate resp. modified release is accomplished.
Characterization of gastric retention drug delivery systems by their release mode is insufficient (claims 5, 12).

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 4, 5, 11, 12.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6, 7	YES
	Claims	1-3, 8-10, 13	NO
Inventive step (IS)	Claims	----	YES
	Claims	1-3, 6-10, 13	NO
Industrial applicability (IA)	Claims	1-3, 6-10, 13	YES
	Claims	----	NO

Citations and explanations (Rule 70.7)

As the applicant has abstained from responding to the Written Opinion, the objections made therein are still maintained:

Both WO 2003/011255 A1 and WO 2003/007916 A1 already refer to gastric retention controlled drug delivery systems composed of a core containing a pressure generating agent and an expandable coating; thus the subject matter of claims 1-3 and 13 is considered to be neither new nor inventive.

WO 2001/010405 A1 discloses a gastric retentive capsule formulation, which is coated with a release retarding agent, e.g. acrylic polymers. Additionally, the capsule contains gas generating agents. Said disclosure prevents both novelty and inventiveness of claims 8-10 and 13.

Claims 6 and 7, which refer to gastric retention systems with two different layers are considered to be new. However, inventiveness cannot be acknowledged for said claims, because due to a lack of disclosure concerning the function of said "first" coating an inventive character of said feature cannot be seen for the present.

Claims 4, 5, 11 and 12: see "Certain claims were found unsearchable".

Industrial applicability is given for claims 1-3, 6-10 and 13.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The agent capable of generating internal pressure (claims 1, 6, 8) as well as the expandable components of the coating (claims 1, 6, 8) are essential features of the present invention; thus they have to be specified within all independent claims.
The formulations "..formed by applying a coating composition.." and "..to form a film ... gastric milleu." (claims 1, 8) represent process features, which are not suitable to characterize a product; thus said formulations should be eliminated (claim 1).
In claim 6 the disclosure of the composition of the first coating is lacking.
In claim 13 the reference to preceeding claims is lacking.

CLAIMS

1. A gastric retention system in the form of a coated tablet comprising :
   (a) a core in the form of a tablet comprising an agent capable of generating internal pressure on the coat, and
   (b) an expandable coating formed by applying a coating composition comprising a film forming polymer and one or more expandable components on the tablet core to form a film capable of expanding and maintaining its physical integrity in the gastric milieu.
2. A gastric retention drug delivery system as claimed in claim 1 wherein the agent capable of generating internal pressure is selected from a group comprising gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof.
3. A gastric retention drug delivery system comprising a gastric retention system as claimed in claim 2 and one or more therapeutically active agents.
4. A gastric retention drug delivery system as claimed in claim 3 wherein one or more therapeutically active agents is present in an immediate release form and/or in a modified release form to provide an immediately releasing dose of one or more of the therapeutically active agents, and/or a modified release dose of the same or different therapeutically active agent(s).
5. A gastric retention drug delivery system as claimed in claim 4 wherein the system has a floatation time of less than 15 minutes, when placed in an aqueous medium.
6. A gastric retention system in the form of a coated tablet comprising:
   (a) a core in the form of a tablet comprising an agent capable of generating internal pressure on the coat, and
   (b) a second coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components on the first coating whereby the second coating forms a film capable of expanding and maintaining its physical integrity in the gastric milieu.
7. A gastric retention drug delivery system comprising a gastric retention system as claimed in claim 6 and one or more therapeutically active agents.
8. A gastric retention system in the form of a coated capsule, comprising :
   (a) a core in the form of a capsule, the core comprising an agent capable of generating internal pressure on the coating, and
   (b) an expandable coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components on the capsule core to

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form a film capable of expanding and maintaining its physical integrity in the gastric milieu.

9. A gastric retention system as claimed in claim 8 wherein the agent capable of generating internal pressure is selected from a group comprising gas generating agents, highly swellable polymers, superdisintegrants and mixtures thereof.

10. A gastric retention drug delivery system comprising a gastric retention system as claimed in claim 9 and one or more therapeutically active agents.

11. A gastric retention drug delivery system as claimed in claim 10 wherein one or more therapeutically active agents is present in an immediate release form and/or in a modified release form to provide an immediately releasing dose of one or more of the therapeutically active agents, and/or a modified release dose of the same or different therapeutically active agent(s).

12. A gastric retention drug delivery system as claimed in claim 10, wherein the system is capable of instantaneously floating, when placed in an aqueous medium.

13. A process for coating a tablet or capsule core comprising applying a coating composition comprising expandable components in a dry powder form or suspended in a non-solvent vehicle.

AMENDED SHEET